

REMARKS

Claims 47, 84-97, 125-132, 134 and 135 are now pending in this application. By this Amendment, claims 125 and 128 are amended. In addition, claims 21-46, 48-50, 53-83, 98-112, 121-124, 133 and 136-140 are canceled without prejudice to, or disclaimer of, the subject matter recited therein.

An Information Disclosure Statement was filed in the above-identified application on April 5, 2001. Applicant received back from the Examiner a copy of the Form PTO-1449 initialed to acknowledge the fact that the Examiner has considered most of the disclosed information. However, the non-patent reference listed on page 1 of the Form PTO-1449 was not initialed to acknowledge consideration of this reference. Thus, the Examiner is requested to initial and return to the undersigned a copy of the subject Form PTO-1449 acknowledging consideration of this reference.

In addition, it is noted that U.S. Patent No. 5,514,178 to Torchio has been cited for the first time in the present Office Action. However, this patent was not listed in a Form PTO-892, as required by the Patent Office. Thus, it is respectfully requested that the Patent Office issue a Form PTO-892 listing U.S. Patent No. 5,514,178 to Torchio.

Entry of the amendments is proper under 37 CFR §1.116 since the amendments: (a) place the application in condition for allowance (for the reasons discussed herein); (b) do not raise any new issue requiring further search and/or consideration (since the amendments amplify issues previously discussed throughout prosecution); (c) do not present any additional claims without canceling a corresponding number of finally rejected claims; and (d) place the application in better form for appeal, should an appeal be necessary. The amendments are necessary and were not earlier presented because they are made in response to arguments raised in the final rejection. Entry of the amendments is thus respectfully requested.

Applicant appreciates the indication that claims 47, 84-97, 134 and 135 are allowed and that claim 128 would be allowed if made independent. Claim 128 is made independent herein. Thus, it is respectfully submitted that claim 128 is now in condition for allowance.

Claims 21-35, 41-46, 48-50, 53-71, 77-83, 98-112, 121-124, 133 and 136-140 are rejected under 35 U.S.C. §103 over Zilber in view of Wolff et al. In addition, claims 38 and 74 are rejected under 35 U.S.C. §103 over Zilber in view of Wolff and Silvestrini. Furthermore, claims 36, 37, 39, 40, 72, 73, 75 and 76 are rejected under 35 U.S.C. §103 over Zilber in view of Wolff and further in view of Yamamoto et al. Although it is Applicant's position that these references do not teach or suggest all of these features of these claims, in an effort to expedite allowance of other claims, claims 21-46, 48-50, 53-83, 98-112, 121-124, 133 and 136-140 have been canceled herein, rendering the rejection of these claims moot.

Claims 125-127 and 129-132 are rejected under 35 U.S.C. §103 over Torchio in view of Wolff. Applicant respectfully traverses the rejection.

Torchio is directed to a prosthesis intended to be introduced into a bodily canal that includes a flexible tube for preserving the normal passage cross-section of the bodily canal and a holding device for immobilizing the flexible tube in position in the canal. See the Abstract. Specifically, Torchio teaches a urethral prosthesis having a first spring 2 constituting the prosthesis proper, which is intended to be accommodated in the bulbo-membranous urethra at the level of a stenosis. Col. 3, lines 10-15. As depicted in Figs. 6 and 12, the level of the stenosis is downstream of the sphincter. In addition, as the holding device, Torchio teaches a spring 5, which is joined to the first spring 2 via a metal wire 4 that traverses the sphincter. The second spring 5 is located upstream of the sphincter. Col. 3, lines 19-30.

Torchio does not teach or suggest that the element designed to be placed upstream of the sphincter, that is, spring 5, has a substantially continuous wall, the wall being fluid-tight with respect to natural fluid flow. In contrast, the helical spring described in Torchio clearly

does not have a fluid-tight wall, particularly considering the bending that occurs in the urethra.

In addition, Torchio does not teach or suggest that the element designed to be placed upstream of the sphincter comprises a therapeutic agent. Furthermore, since the device described in Torchio is designed to treat a condition that is downstream of the sphincter, there would have been no motivation to modify the device described in Torchio to include a therapeutic agent on the element that is designed to be placed upstream of the sphincter.

In an effort to emphasize the fact that the element located upstream of the sphincter contains the therapeutic agent, claim 125 has been amended to recite that this element is bio-active. However, it is respectfully submitted that this amendment does not change the scope of claim 125 since it already recited that this element comprises a therapeutic agent that causes reduction of the obstruction.

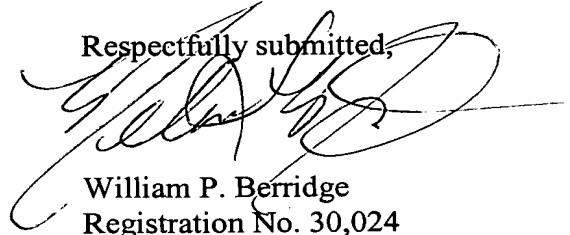
Wolff does not overcome the deficiencies of Torchio. In particular, although Wolff teaches a drug eluting prosthesis, Wolff does not provide any motivation to include a drug in the element of Torchio that is located upstream of the sphincter, the device in Torchio being designed to treat a condition downstream of the sphincter. In addition, Wolff does not teach or suggest a prosthesis having a non-biodegradable tubular element having a substantially continuous wall, the wall being fluid-tight with respect to natural fluid flow.

Torchio in view of Wolff do not teach or suggest the invention of claim 125. Therefore, the rejection of claim 125 and of claims 126, 127 and 129-132, which depend from claim 125, should be reconsidered and withdrawn.

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of claims 47, 84-97, 125-132, 134 and 135 are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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